IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

AMERICAN HOSPITAL ASSOCIATION, et al.,	§	
Plaintiffs,	§	
v.	§	No. 4:23-cv-1110-P
BECERRA, et al.,	§	
Defendants.	§	

PLAINTIFFS' COMBINED BRIEF IN OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND REPLY BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Jonathan D. Guynn (TX 24120232)
JONES DAY
2727 N. Harwood St., Ste. 500
Dallas, Texas 75201
(214) 220-3939
(214) 969-5100 (fax)
jguynn@jonesday.com

Hashim M. Mooppan* (DC 981758)
Rebekah B. Kcehowski* (PA 90219)
Audrey Beck* (DC 1739917)
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939
(202) 626-1700 (fax)
hmmooppan@jonesday.com
rbkcehowski@jonesday.com
abeck@jonesday.com
* *Pro hac vice*

Counsel for Plaintiffs

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INTRODUCTION AND SUMMARY

Recognizing that its Original Bulletin was legally indefensible, HHS responded to this suit by issuing a Revised Bulletin just days before its brief was due. But the agency's inconsequential modifications only confirmed that *both* agency actions were substantively and procedurally unlawful. The unprecedented rule HHS has adopted is unmoored from statutory text and purpose, as well as practically unworkable and internally inconsistent—unsurprising for a rule hastily reformulated in the crucible of litigation and still critically lacking in public feedback. Just like the Original Bulletin, the Revised Bulletin will prevent healthcare providers from communicating vital health information to the communities they serve. Faced with the threat of civil penalties, the Plaintiff Hospitals and the members of Plaintiff Associations (Plaintiffs) had no choice but to comply with this unlawful government mandate. Yet several federal agencies—including one within HHS itself—continue to engage in the very conduct that the Revised Bulletin purportedly reminds them has always been illegal. The Court should put an end to this embarrassing saga of regulatory overreach and bar enforcement of HHS's unlawful and unwise new rule.

The Original Bulletin created an unqualified rule providing that when an online technology connects (1) an individual's IP address with (2) a visit to an Unauthenticated Public Webpage that addresses specific health conditions or healthcare providers, that combination of information (the Proscribed Combination) is "individually identifiable health information" (IIHI) subject to HIPAA's disclosure restrictions. *See* AR 22; *see also* AR 20-21; Pltfs. Br. 6-7 & n.2. That new substantive rule violates the IIHI definition's plain text. Even assuming (without conceding) that this "information" "received" by the page owner provides a "reasonable basis to believe it can be used to identify the individual" who visited the page, it does not "relate[] to" that individual's "health," "health care," or "payment for … health care," 42 U.S.C. § 1320d(6), given the many possible reasons to visit such pages. At most, the website metadata comprising the Proscribed

Combination shows that the page owner "received" "information" revealing an identifiable individual visited a health-related page. But *that alone* does not show *why* the individual visited the page and thus discloses nothing about the individual's own health. In other words, the "information" "received" is not "related" to the individual's own health because, by itself, it does not show that the individual visited the page *because of* something concerning his own health.

Notably, in the Revised Bulletin, HHS agrees with Plaintiffs, belatedly recognizing that the Proscribed Combination is not itself IIHI. The Revised Bulletin states that "the mere fact that an online tracking technology connects the IP address of a user's device (or other identifying information) with a visit to a webpage addressing specific health conditions or listing health care providers is not a sufficient combination of information to constitute IIHI…." AR 4. Moreover, the Revised Bulletin adds an example—where the identifiable individual visiting the health-related webpage is a student doing research unrelated to his own health—confirming that the Proscribed Combination alone is not IIHI. AR 6. And the Revised Bulletin eliminates the Original Bulletin's erroneous example of the Proscribed Combination alone being IIHI. *Compare* AR 22 (appointment-search example), *with* AR 6 (example removed). In short, HHS has conceded that the rule adopted in the Original Bulletin exceeded the scope of its authority under HIPAA.

The agency's retreat does not go far enough, however, to fix the rule's fatal flaws. The Revised Bulletin's modified rule for what constitutes IIHI remains essentially the same. HHS only tweaked the Proscribed Combination to require that the identifiable individual's *subjective* reason for visiting the health-related public page must be related to his own health. Specifically, the Revised Bulletin states (with a double negative removed) that the Proscribed Combination "is ~~not~~ a sufficient combination of information to constitute IIHI if the visit to the webpage is ~~not~~ related to [the] individual's past, present, or future health, health care, or payment for health care." AR 4.

So, as the Government's brief affirmatively restates the Revised Bulletin's modified rule, "identifying information about users who *are* visiting the webpage for their health care needs constitutes IIHI." *See* Defts. Br. 31. And as the Government recognizes, "the Revised Bulletin makes this [rule] plain" through another "example[]"—involving a cancer patient "looking at [an oncology-services] webpage 'to seek a second opinion on treatments for their brain tumor.'" *See id.* at 31-32 (quoting AR 6). In that example, unlike the one involving the student researcher, the Government contends that the visit would disclose PHI because the individual's undisclosed reason for visiting the oncology-services page related to his health as a cancer patient. But this subjective-motivation gloss on the Proscribed Combination is a distinction without a difference.

Textually, the Revised Bulletin flouts the critical element in the statutory definition of IIHI that the "information" that "relates to" the identifiable individual's health must be "created or received" by the covered entity. 42 U.S.C. § 1320d(6). The Revised Bulletin instead provides that the mere fact that an identifiable individual visited a health-related webpage becomes IIHI if the individual's *subjective reason* for visiting the page related to his own health, *whether or not* the page owner receives this additional piece of information. Although it is possible that the individual could also self-disclose his reason on the page (*e.g.*, by identifying symptoms as his own or booking an appointment for himself with a provider), *see* Defts. Br. 2, 17, 28, the Revised Bulletin applies even if he does not. As the cancer-patient example shows, so long as an identifiable individual's "visit" to a health-related public webpage is *in fact* "related" to his own health, the Revised Bulletin deems IIHI to be collected even though the page owner *did not receive that information about the visit's purpose*. *See id.* at 32 (citing AR 6). Yet the "information" that an identifiable individual visited a health-related page—which HHS now concedes does not alone "relate[] to" the individual's health—cannot somehow become related to the individual's health

through the artifice of combining it with additional "information" about the individual's subjective motive that the page owner does not actually "receive[]." 42 U.S.C. § 1320d(6).

Practically, the Revised Bulletin leads to nonsensical results. HIPAA strikes a balance between protecting personal-health privacy and sharing public-health information. *See* Pltfs. Br. 1-2. Treating metadata that *reveals nothing* about a user's own health as protected "health information" destroys that balance. Disclosing the metadata to third-party technology vendors at most reveals that an identifiable individual visited a health-related page—*not* the unknown reasons why he did so or what any unknown health condition he has may be.

Moreover, the effect of the agency's position is overbroad. As the Government concedes, "[c]ommon sense dictates that at least some users who visit" health-related webpages "are doing so … [for] reasons related to their own health care," but many others "are not." *See* Defts. Br. 30-31. And because webpage owners *do not know* which category any particular user falls into unless they receive that information too, they cannot apply the Revised Bulletin's test. As the Government cheerfully admits, "the only way to ensure" that online tools on such pages "are not disclosing PHI" under the Revised Bulletin is to treat *all* user-identifiable information as IIHI protected from disclosure—even though that will also "prevent disclosures of non-IIHI." *See id.* at 31. That the Revised Bulletin will effectively regulate "non-IIHI" is a sure sign that HHS has grievously misconstrued the IIHI definition. In fact, HHS's disingenuous change is no change at all. The agency has just gone from erroneously saying that the Proscribed Combination is *always* IIHI to saying that it *inevitably* will be IIHI in at least some *unidentifiable* cases, so hospitals had better treat it as IIHI in *all* cases to remain HIPAA-compliant.

Further, the agency's position is internally inconsistent and contrary to settled practice. Like the Original Bulletin, the Revised Bulletin asserts that "identifying information showing [a

user's] visit to" hospital webpages that simply contain generic information like "visiting hours" is not IIHI because such information does not "relate[] to" the user's own health. AR 6; *see* AR 22. But under the Revised Bulletin's misguided logic, that should not be so if the user's "visit is [nevertheless] related to" his own health—*e.g.*, if the individual in the cancer-patient example uses his personal laptop to look up when his family can visit him during his treatments. *See* AR 6. Regardless of whether that individual is visiting the oncology-services page or the visiting-hours page, his *subjective reason* for visiting the page is related to his health, but the *objective metadata* received showing the mere fact of the visit is not. The agency's proper concession as to the visiting-hours page thus forecloses its position as to the oncology-services page.

Indeed, other federal agencies covered by HIPAA use third-party technologies on their own health-related webpages. *See* Pltfs. Br. 9-10. Yet under HHS's position, those agencies are all improperly disclosing IIHI because "at least some users who visit these webpages … are doing so … [for] reasons related to their own health care." *See* Defts. Br. 30. Astonishingly, the Government *essentially agrees* that HHS has made outlaws of these agencies. *See id.* at 34-35 ("[T]he Revised Bulletin reminds them to protect that information consistent with" HIPAA). Even more astonishingly, one of them is an HHS sub-component (CMS). *See* Compl. ¶ 10.

These legal flaws are more than sufficient to establish that HHS exceeded its statutory authority. In addition, the Revised Bulletin, like the Original Bulletin, is unlawful because it has arbitrary-and-capricious reasoning and failed to go through notice-and-comment rulemaking. In fact, the Revised Bulletin is *even worse* on both fronts. HHS failed to meaningfully consider any of the key legal and policy concerns that Plaintiffs raised about the Original Bulletin. And HHS was fully aware that its new legal rule concerning the Proscribed Combination is having a significant effect on private parties, which requires providing them an opportunity for input.

Finally, there is no jurisdictional obstacle to this Court's review of Plaintiffs' claims. The APA's final-agency-action requirement is easily satisfied because the novel rule that HHS has definitively adopted is coercing covered entities to refrain from lawful conduct under threat of civil penalties. The Government's contrary arguments mischaracterize both the agency's actions and the Fifth Circuit's precedents. Moreover, even if the APA were unavailable, this Court at least has the power to grant injunctive and declaratory relief against HHS for exceeding its authority under HIPAA. The Government's breathtaking position that this Court can do nothing to stop an agency from breaking the law in a way that is injuring private parties is anathema to the separation of powers and refuted by the history of judicial review of agency action.

ARGUMENT

I. THIS COURT HAS JURISDICTION OVER PLAINTIFFS' CLAIMS

Although the Government contests this Court's jurisdiction, it does so only on one narrow ground—that the Revised Bulletin is not final agency action under the APA. *See* Defts. Br. 15. That objection is erroneous under settled precedent, especially given the manner in which the Revised Bulletin modified the Original Bulletin. There is thus no procedural barrier to this Court's resolving the merits of Plaintiffs' claims that HHS (1) exceeded its statutory authority, (2) acted arbitrarily and capriciously, and (3) failed to use notice-and-comment rulemaking.

Moreover, even if the APA's finality requirement were not satisfied, that would only prevent Plaintiffs from raising the latter two claims under the APA cause of action. It would not deprive this Court of jurisdiction to adjudicate non-APA causes of action raising Plaintiffs' primary claim that HHS exceeded its statutory authority under HIPAA. Nor would it deprive this Court of power to grant injunctive relief under its equitable jurisdiction and declaratory relief under the Declaratory Judgment Act.

To be clear, this Court need not consider the non-APA causes of action because the Revised Bulletin is plainly final agency action under the APA. But if this Court were to conclude otherwise, it should know that the Government repeatedly misstates the law governing non-APA review of illegal executive action. Plaintiffs regret having to spend more than a dozen pages exposing the myriad errors in the Government's non-APA arguments, but those arguments would upend decades of precedent that allow private parties to prevent government agencies from exceeding their statutory authority. Whether through the APA or otherwise, this Court should reject the Government's cynical attempt to evade judicial review of regulatory overreach.

A. Plaintiffs Can Invoke The APA's Cause Of Action Because The Original Bulletin Was, And The Revised Bulletin Is, Final Agency Action

To the extent that Plaintiffs rely on the APA's general cause of action in 5 U.S.C. § 704, they must satisfy its "final agency action" requirement. *See Apter v. HHS*, 80 F.4th 579, 593 (5th Cir. 2023). As Plaintiffs have explained, a rule is "final" for APA purposes if it (1) marks the consummation of the agency's decisionmaking process; and (2) determines rights or obligations or causes legal consequences to flow. *See* Pltfs. Br. 24. Here, finality exists because HHS's rule—that the use of online technologies collecting the Proscribed Combination always or inevitably discloses IIHI—is definitive, novel, and has binding impacts on regulated entities and the agency itself. *See id.* at 24-27. The Government's contrary arguments all fail. *See* Defts. Br. 15-21.

1. Original Bulletin. For starters, the Government tries to skip to the Revised Bulletin because it cannot meaningfully dispute that the Original Bulletin was final agency action when this suit was filed. *See id.* at 15. To be sure, the Government briefly suggests that the Original Bulletin merely "outline[d] one hypothetical situation in which a tracking technology vendor would *likely* have access to PHI in the context of an unauthenticated webpage." *See id.* at 16-17 (emphasis added). But that flagrantly mischaracterizes the Original Bulletin, which

unambiguously stated that the example *did* involve PHI disclosure, not just that it "likely" would. In particular, the Original Bulletin stated: "For example, tracking technologies could collect an individual's email address and/or IP address when the individual visits a regulated entity's webpage to search for available appointments with a health care provider. *In this example*, the regulated entity *is disclosing PHI* to the tracking technology vendor, and thus *the HIPAA Rules apply*." AR 22 (emphasis added).

The fact that this example was "divorced from the factual context of any particular case" (Defts. Br. 16) proves Plaintiffs' point: the Original Bulletin clearly adopted an unqualified legal rule that when an online technology connects (1) an individual's IP address with (2) a visit to an Unauthenticated Public Webpage that addresses specific health conditions or healthcare providers, the receipt of that information *itself* is IIHI. *See* AR 22. That "definitive position" of HHS in construing HIPAA's IIHI definition satisfies the finality test's first prong. *Nat'l Pork Producers Council v. EPA*, 635 F.3d 738, 755 (5th Cir. 2011); *accord Texas v. Becerra*, 623 F. Supp. 3d 696, 720 (N.D. Tex. 2022) (*Becerra I*), *aff'd*, 89 F.4th 529, 538 (5th Cir. 2024).

As for the second prong, HHS's definitive position clearly "create[d] new … obligations," rather than "merely restat[ing]" HIPAA's requirements. *Nat'l Pork Producers*, 635 F.3d at 756. After all, the Revised Bulletin admits the Original Bulletin *misstated* HIPAA's requirements: "the mere fact that an online tracking technology connects the IP address of a user's device (or other identifying information) with a visit to a webpage addressing specific health conditions or listing health care providers is *not* a sufficient combination of information to constitute IIHI …." AR 4 (emphasis added). Indeed, HHS deleted the erroneous appointment-search example *and* conceded that information simply showing visits to such pages by identifiable individuals would not be IIHI "if the visit is not related to" the individual's own health. AR 6; *accord id.* (providing example

where information disclosing that an identifiable individual visited oncology-services page "would not constitute a disclosure of PHI" if the individual was "a student … writing a term paper").

In sum, the Original Bulletin was final agency action when this suit was filed, and Plaintiffs properly invoked the APA to challenge it. Nor were Plaintiffs' claims against the Original Bulletin mooted by the Revised Bulletin, and the Government does not argue otherwise. *See infra* at 14-15 & n.3. This Court thus indisputably has jurisdiction to hear those claims.

2. Revised Bulletin. The Government fares no better in contesting the Revised Bulletin's status as final agency action. The Revised Bulletin's tweak to the Original Bulletin is still a definitive position and effectively the same one. As discussed, the Revised Bulletin retains its rule against the Proscribed Combination, adding only a subjective-motivation gloss that is immaterial for purposes of APA finality. More specifically, the Revised Bulletin states that "the mere fact that an online tracking technology connects the IP address of a user's device (or other identifying information) with a visit to a webpage addressing specific health conditions or listing health care providers *is* … a sufficient combination of information to constitute IIHI *if* the visit to the webpage is … related to" the individual's own health. AR 4 (emphasis added; double negative omitted). To illustrate what "is a disclosure of PHI" because the identifiable individual's "visit" is "related" to his own health, the Revised Bulletin replaces the appointment-search example with the example of an individual "looking at a hospital's webpage listing its oncology services to seek a second opinion on treatment options for their brain tumor." AR 6. And the Government's brief cites that example as "mak[ing] … plain" that "identifying information about users who *are* visiting the webpage for their health care needs constitutes IIHI." *See* Defts. Br. 31.

Accordingly, the Government refutes its own assertion that the Revised Bulletin does not "assert a final position on any factual circumstances." *See id.* at 16 (cleaned up). Indeed, the

suggestion that additional facts may matter "is a red herring." *See id.* at 30. The Government correctly notes that "[c]ommon sense dictates that at least some users who visit" public webpages addressing specific health conditions or healthcare providers "are doing so … [for] reasons related to their own health care." *See id.* So the Revised Bulletin still adopts a "definitive position"—that the use of online technologies collecting the Proscribed Combination will *inevitably* disclose IIHI. *See Nat'l Pork Producers*, 635 F.3d at 755. After all, if Plaintiffs were to use an online technology that collects identifiable information about visitors to an oncology-services page, the agency's position would be clear without any additional facts: "at least some" of the information would be IIHI and thus HIPAA's requirements would apply to this use of the online tool. By contrast, the precedents invoked by the Government do not involve this type of definitive agency interpretation of the statutory obligations applicable to all participants in a regulated field.[1]

Nor can the Government plausibly argue that the Revised Bulletin "merely reiterates the Privacy Rule's longstanding restrictions on the use and disclosure of PHI." *See* Defts. Br. 17. Although "it has always been true that regulated entities may not impermissibly disclose PHI to tracking technology vendors," *id.*, the question here is not how HIPAA regulates PHI collected by online tools, but *what counts as PHI* collected by online tools. On the merits, Plaintiffs will address in detail why the Revised Bulletin's (mis)interpretation of the IIHI definition in this context would work a radical (and flawed) change to the law. *See* Part III, *infra*. But for final-agency-action

[1] *See Louisiana State v. U.S. Army Corps of Engineers*, 834 F.3d 574, 581-82 (5th Cir. 2016) (report about deauthorizing agency project was "interlocutory" because it was contingent on obtaining separate agreement with third-party State); *Exxon Chems. Am. v. Chao*, 298 F.3d 464, 466-67 (5th Cir. 2002) (order of agency adjudicatory board "remand[ing] a case for further fact-finding and consideration" was not "a decision definitively resolving the merits of [the party's] case"); *cf. Prof'ls & Patients for Customized Care v. Shalala*, 56 F.3d 592, 596-97 (5th Cir. 1995) (holding that compliance policy guide was not substantive rule subject to APA's notice-and-comment requirement because it merely announced "nine factors" that agency "will consider" in "determining whether to initiate an enforcement action," while expressly emphasizing that "list of factors [was] not intended to be exhaustive").

purposes, Plaintiffs need only establish that the Revised Bulletin goes beyond merely restating existing law and imposes legal consequences on regulated parties. *See* Pltfs. Br. 25-27.

The following four points easily make that showing:

(1) Neither the Revised Bulletin nor the Government's brief cites any prior agency pronouncement even construing the IIHI definition in the specific context of information collected by online technologies—let alone adopting the agency's new rule on the Proscribed Combination. *See* AR 4-7; Defts. Br. 17;

(2) The administrative record and the Government's brief show that there are "significant differences in how regulated entities implemented the requirements of the HIPAA Rules in the context of online tracking technologies" because, among other things, many entities disagree with HHS's new view of when IIHI is disclosed. *See* Defts. Br. 10 (citing, *e.g.*, AR 347-49); *accord* Pltfs. SJ Appx. 26 ("Prior to the Bulletin, and consistent with the longstanding practice of AHA members …, AHA did not understand the Proscribed Combination to constitute IIHI.");

(3) Several courts have rejected the agency's interpretation, and the Government's sole rejoinder is that "[t]he Court should decline to follow them." *See* Defts. Br. 34; and

(4) It is undisputed that HIPAA-covered federal agencies are disclosing IIHI in violation of the Revised Bulletin's new rule, and the Government's only response is that "the Revised Bulletin reminds them to protect that information." *See id.* at 34-35.

Given that the rule HHS has created comes as shocking news to regulated entities, courts, and even other federal agencies, the Government cannot be serious when it insists that the Revised Bulletin does not "break[] new ground." *See id.* at 17. As the Fifth Circuit held just a few months ago in a case about another novel HHS rule masquerading as a "remind[er]," this guidance document "is new policy" because it has "caused a sea change in the law" by "set[ting] out HHS's legal position—for the first time—regarding how [HIPAA] operates" in a particular context. *Texas v. Becerra*, 89 F.4th 529, 535, 541 (5th Cir. 2024) (*Becerra II*). Under agency action like this, "[l]egal consequences flow," and "rights and obligations" are "determine[d]," *id.* at 541, because "affected private parties are reasonably led to believe that failure to conform will bring adverse consequences" in enforcement actions, *Texas v. EEOC*, 933 F.3d 433, 442 (5th Cir. 2019).

The Government responds—quoting *Luminant Generation Co. v. EPA*, 757 F.3d 439, 442 & n.7 (5th Cir. 2014)—that the Revised Bulletin "merely expresses its view of what the law requires," and that the legal duties instead flow from HIPAA's implementing regulations, which would be the authority invoked by HHS if it brought an enforcement action. *See* Defts. Br. 18. But this response ignores that the Fifth Circuit has repeatedly explained that *Luminant* involved a notice of violations "comment[ing] on a single [company]'s practices," and that *Luminant* is thus inapposite where an agency "tells [its] staff and all [regulated parties] what sort of policy is unlawful." *Becerra II*, 89 F.4th at 539 (quoting *EEOC*, 933 F.3d at 445). As should not have needed to be said yet again, unlike in *Luminant*, the Revised Bulletin's rule against the Proscribed Combination governs HHS staff and all HIPAA-covered entities.[2]

The Government is likewise wrong that final agency action "would come only after an investigation by OCR and a separate administrative enforcement proceeding." *See* Defts. Br. 16. Even before that, an agency's action is final where it "has the effect of committing the agency itself to a view of the law that, in turn, forces the plaintiff either to alter its conduct[] or expose itself to potential liability." *EEOC*, 933 F.3d at 446. That is precisely the effect of the Revised Bulletin, as the threat of civil penalties is chilling Plaintiffs from using online technologies on their Unauthenticated Public Webpages. *See* Pltfs. Br. 12. Given that injurious effect on their conduct, Plaintiffs must be able to seek judicial review now, as they will not be subject to reviewable civil penalties later. Put another way, the Revised Bulletin "hang[s] over Plaintiffs' heads like the sword

[2] The remaining precedents cited by the Government are even further afield. *See Nat'l Pork Producers*, 635 F.3d at 756 (agency guidance letters "d[id] not change any rights or obligations" because court viewed them as "only reiterat[ing] what ha[d] been well-established since the enactment of the [underlying statute]" decades earlier); *Peoples Nat. Bank v. Office of Comptroller of Currency*, 362 F.3d 333, 337 (5th Cir. 2004) ("intra-agency procedural rule" concerning "scope of review" within anticipated administrative appeal was not "final agency action" because party must "pursue its administrative appeal, not shortcut it by filing suit").

of Damocles," and thus it would be plainly "inadequate" to force them to violate the new rule and then "sit and 'wait for the Agency to drop the hammer.'" *Texas v. HHS*, No. 23-CV-22, 2023 WL 4629168, at *9-10 (W.D. Tex. July 12, 2023) (quoting *Sackett v. EPA*, 566 U.S. 120, 127 (2012)).

In sum, like the Original Bulletin, the Revised Bulletin is final agency action. Plaintiffs therefore may invoke the APA cause of action to challenge the Revised Bulletin on both substantive and procedural grounds under the APA. The Government raises no other jurisdictional objection to this Court's review of any of those claims.

B. The APA's Finality Requirement Is Not Jurisdictional, And The Government Does Not Contest Any Of The Constitutional Or Statutory Requirements For This Court To Exercise Jurisdiction Over Plaintiffs' Claims

In addition to being clearly incorrect, the Government's final-agency-action argument is also largely irrelevant. The APA's finality requirement is not jurisdictional, and the failure to satisfy it would not affect this Court's authority to grant relief on Plaintiffs' non-APA causes of action. We address the first point here in Part I.B, and the second point next in Part I.C. Importantly, if the Court agrees that the APA's finality requirement has been satisfied, *see* Part I.A, *supra*, it can move past this entire discussion and proceed to the merits, *see* Parts II-IV, *infra*.

The Government commits a basic category error in arguing that this Court would "lack jurisdiction" if the APA's finality requirement were not satisfied. *See* Defts. Br. 15. "Because [the APA's] declaration that final agency action is 'subject to judicial review' is not a grant of jurisdiction," the absence of final agency action "would not deprive a federal court of any jurisdiction it otherwise has"—instead, it would merely prevent the plaintiff from invoking the APA's "limited cause of action" to sue. *Trudeau v. FTC*, 456 F.3d 178, 183-84 (D.C. Cir. 2006); *see Steel Co. v. Citizens for Better Environment*, 523 U.S. 83, 89 (1998) ("It is firmly established in our cases that the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, *i.e.*, the courts' statutory or constitutional *power* to adjudicate the

case."). Indeed, the Fifth Circuit reaffirmed just last year in *Apter* that "there is no requirement of 'finality'" under the APA "when judicial review is sought pursuant to" another "cause of action that arises completely apart from the general provisions of the APA." 80 F.4th at 591. Although the Government cites a different Fifth Circuit case that described the final-agency-action requirement as jurisdictional, *Qureshi v. Holder*, 663 F.3d 778, 781 (5th Cir. 2011), the plaintiffs there do not appear to have raised a non-APA cause of action, and thus the court did not address the distinction between lack of a cause of action and lack of jurisdiction. *See* Defts. Br. 15. Unlike *Apter*—where the distinction mattered and was applied—*Qureshi* is just another opinion that "loosely" used a drive-by "jurisdictional" characterization because the word has "many, too many, meanings." *Trudeau*, 456 F.3d at 184 (quoting, indirectly, *Steel Co.*, 523 U.S. at 80).

By contrast, there are three *actual jurisdictional* requirements that must be met for this Court to adjudicate Plaintiffs' claims. Plaintiffs' opening brief demonstrated that each of them is satisfied, and the Government raises no objection as to *any* of them.

First, the Government tacitly concedes that an Article III controversy exists. It does not dispute that Plaintiffs had standing to challenge the Original Bulletin when they filed their complaint, given the credible threat that HHS would take enforcement action against them if they were to use online technologies that collect the Proscribed Combination on their Unauthenticated Public Webpages. *See* Pltfs. Br. 12-13. Likewise, the Government does not contest Plaintiffs' standing to challenge the Revised Bulletin now, and it could not plausibly do so. The same credible threat of enforcement exists because HHS adheres to its essential position that the use of online technologies collecting the Proscribed Combination discloses IIHI—just *inevitably*, rather than *always*. *See* Defts. Br. 30-31; AR 6, 22. Nor does the Government contend that issuance of the Revised Bulletin rendered Plaintiffs' challenge to the Original Bulletin moot. *See* Defts. Br. 3 n.2.

Any such contention would be foreclosed by the voluntary-cessation doctrine, especially given the ephemeral change in the agency's position.[3] In sum, the Government acknowledges that there is an Article III controversy between Plaintiffs and Defendants over both versions of the Bulletin.[4]

Second, the Government tacitly concedes that the United States has waived any sovereign immunity. It does not dispute that Plaintiffs' claims are covered by the sovereign-immunity waiver in 5 U.S.C. § 702, because Plaintiffs seek non-monetary relief, challenge an agency "rule" that is plainly "agency action" (whether or not it is "final"), and fall within the "zone of interests" that Congress sought to protect by limiting the scope of HIPAA's IIHI definition. *See* Pltfs. Br. 13-15.

Third, the Government tacitly concedes that two different statutes give this Court subject-matter jurisdiction over Plaintiffs' claims. It does not dispute that 28 U.S.C. § 1346(a)(2) confers

[3] *See, e.g.*, *FBI v. Fikre*, 144 S. Ct. 771, 778 (2024) (rejecting mootness due to government's failure to carry its "formidable" "'burden to establish' that it cannot reasonably be expected to resume *its* challenged conduct"); *Ne. Fla. Chapter, Associated Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 662 (1993) (holding that voluntary-cessation doctrine applied "a fortiori" where government "repeal[ed] the challenged statute [but] replac[ed] it with one that differ[ed] only in some insignificant respect"); *Speech First, Inc. v. Fenves*, 979 F.3d 319, 327-29 (5th Cir. 2020) (holding that university's "recent revisions" that "eliminated" the challenged "language" in a school policy did not satisfy voluntary-cessation doctrine because, among other things, post-litigation "timing of the University's policy amendments" was "suspicious" and university "ha[d] not issued a controlling statement of future intent" not "to reenact" old policy).

[4] The Government's amicus—an anonymous patient represented by her class-action counsel—nevertheless raises an Article III objection. She contends that Plaintiffs seek an advisory opinion about a "hypothetical state of facts" that will "redress no alleged harm," based on her assertion that online technologies are not "limited" to disclosing the Proscribed Combination and transmit "far more information than" that. *See* Doe Br. 7-8. This objection is frivolous three times over. *First*, the rule HHS has adopted is that disclosure of the Proscribed Combination alone, *even without any other information disclosed*, will always or inevitably disclose IIHI, and Plaintiffs have submitted *uncontested declarations* that the adoption of *that rule* is what is chilling them from using online tools on their Unauthenticated Public Webpages. *See* Pltfs. Br. 10-11. So they have standing because their actual injury will be redressed by stopping HHS's enforcement of that rule. *See id.* at 11-12. *Second*, while the Government's amicus claims that online technologies on the Unauthenticated Public Webpages of Plaintiffs' *amici* disclose more information than just the Proscribed Combination, *see* Doe Br. 4-7, she does not and cannot claim that such technologies *necessarily* disclose information *related to an identifiable user's own health*. And that is why *Plaintiffs could and would use* such technologies on their webpages if the agency's unlawful rule were set aside. *Finally*, in all events, standing must be assessed based on "the manner and degree of evidence required at the [applicable] stage[] of litigation," and the sources cited in the brief of the Government's amicus are not "affidavit[s] or other evidence" that can "controvert[]" Plaintiffs' standing declarations "for purposes of the summary judgment motion[s]." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992).

original jurisdiction over this civil action asserting federal claims (under HIPAA and the APA) against the United States pursuant to the sovereign-immunity waiver in 5 U.S.C. § 702. *See* Pltfs. Br. 13. Nor does it dispute that 28 U.S.C. § 1331 confers original jurisdiction over "all civil actions arising under the … laws … of the United States," which unambiguously applies to Plaintiffs' claims asserting that HHS has contravened HIPAA and the APA. *See* Pltfs. Br. 13.

In sum, even if the APA's final-agency-action requirement were not satisfied, this Court's jurisdiction would still be beyond dispute. To be sure, Plaintiff would be unable to invoke the APA's *cause of action* to assert claims arising solely under the APA—*i.e.*, their alternative claims that HHS offered arbitrary-and-capricious reasoning and failed to go through notice-and-comment rulemaking. *See Apter*, 80 F.4th at 593. But they could still assert any "cause of action that arises completely apart from the general provisions of the APA." *See id.* at 591. So the real question would be whether there is a *non-APA* cause of action available to raise their primary claim that HHS has exceeded its statutory authority under HIPAA.

C. Even Without Final Agency Action Under The APA, Plaintiffs Have Causes Of Action To Obtain Injunctive And Declaratory Relief Against HHS For Exceeding Its Authority Under HIPAA

Wholly apart from the APA, when a federal agency exceeds its statutory authority, federal courts generally have authority to review and restrain such unlawful action. Here, if this Court agrees that HHS extended HIPAA's IIHI definition to cover information that is *not* IIHI, it has well-established power to grant injunctive and declaratory relief to redress Plaintiffs' injuries from that overreach. The Government's contrary arguments all fail once again. *See* Defts. Br. 21-26.

1. Injunctive relief. When a federal court has subject-matter jurisdiction over a claim alleging "violations of federal law by federal officials"—as this Court indisputably does, *see* Part I.B, *supra*—it may "grant injunctive relief," even absent specific statutory authorization, pursuant to its general powers as a "court[] of equity." *Armstrong v. Exceptional Child Center, Inc.*, 575

U.S. 320, 326-27 (2015). This power long pre-dates the APA. In a seminal case, the Supreme Court held that "[t]he acts of all [federal] officers must be justified by some law, and in case an official violates the law to the injury of an individual[,] the courts generally have jurisdiction to grant relief." *Am. Sch. of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 108 (1902); *see Fed. Ex. Corp. v. Dep't of Comm.*, 39 F.4th 756, 763-64 (D.C. Cir. 2022) (observing that *McAnnulty* is "commonly cited as the wellspring of nonstatutory review of agency action"). In *McAnnulty*, because the Postmaster General had directed a subordinate "to retain and refuse to deliver [certain] letters" based on "a mistaken view of the law" banning mail-fraud schemes, the Court ordered entry of an "injunction to prohibit the further withholding of the mail." 187 U.S. at 110.

Although the Government acknowledges this pre-APA authority, it suggests that the APA somehow displaced or modified the power. *See* Defts. Br. 22. But "nothing in the subsequent enactment of the APA altered the *McAnnulty* doctrine of review." *Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322, 1328 (D.C. Cir. 1996); *see, e.g.*, *Harmon v. Brucker*, 355 U.S. 579, 581-82 (1958) (per curiam) (citing *McAnnulty* and reaffirming that, "[g]enerally, judicial relief is available to one who has been injured by an act of a government official which is in excess of his express or implied powers"). The Government fails to identify any APA provision that purports to reduce federal courts' pre-APA equitable powers to enjoin unlawful actions by federal officials. Exactly the opposite: the APA's cause of action for judicial review of "final agency action" not "made reviewable by statute" is available *only* where "there is no other adequate remedy in a court." 5 U.S.C § 704. Thus, "[f]ar from displacing judicial review that occurs outside of the APA regime[,] … the APA expressly acknowledges that this review survives." *Duncan v. Muzyn*, 833 F.3d 567, 577 (6th Cir. 2016); *see Hecht Co. v. Bowles*, 321 U.S. 321, 330 (1944) (warning against "lightly impl[ying]" that Congress intends "major departure[s]" from "long tradition" of "equity").

Ignoring all of that, the Government contends that the Fifth Circuit "has expressed significant doubt" about whether "*ultra vires* review survived the 1976 amendments to the APA," which enacted the sovereign-immunity waiver in 5 U.S.C. § 702. *See* Defts. Br. 22 (citing *Geyen v. Marsh*, 775 F.2d 1303 (5th Cir. 1985)). But the Government gets things backwards. In *Geyen*, the question was whether a suit against a federal official for his official acts was subject to the six-year statute of limitations applicable to suits "against the United States." 775 F.2d at 1306. The Court held that the answer was yes because "[a]ctions challenging official conduct are intrinsically against the United States." *Id.* at 1306-07. And it further reasoned that § 702's waiver of sovereign immunity had obviated the need to instead "indulge[] in the fiction that a federal official acting … beyond his statutory powers was acting for himself only and not as an agent of the government." *Id.* at 1307. Nothing in *Geyen* suggests that the APA's sovereign-immunity waiver somehow *limited* the pre-APA equitable powers of courts to enjoin unlawful agency action. That would be perverse "[s]ince it is undisputed that the 1976 amendment to § 702 was intended *to broaden* the avenues for judicial review of agency action." *Bowen v. Massachusetts*, 487 U.S. 879, 891-92 (1988) (emphasis added). Rather, § 702's sovereign-immunity waiver means that plaintiffs can seek non-statutory equitable relief for unlawful agency action *directly* against the United States, not just *indirectly* against its officers. *See Apter*, 80 F.4th at 589, 593.

The Government alternatively contends that non-statutory equitable relief for unlawful agency action is unavailable for "a garden-variety argument that an agency misinterpreted the operative statutory language." *See* Defts. Br. 23. It says that, instead, "an *ultra vires* claim" is limited to "egregious" situations of "blatantly lawless" action, such as when an agency acts "without any authority whatsoever" or contrary to "a specific and unambiguous statutory" limitation. *See id.* at 22-23 (cleaned up). But that characterization of the scope of non-statutory

equitable relief is irreconcilable with *McAnnulty*, which the Government tellingly never cites. As noted, the Court there ordered entry of an injunction to correct the Postmaster General's merely "mistaken view of the law" that certain letters were covered by the mail-fraud ban, which was an ordinary "legal error" that a court sitting in equity could correct. 187 U.S. at 110-11.

The Court nowhere suggested the type of heightened merits standard the Government proposes. Although it did once describe the Postmaster General's "mistake of law" as "clear," that stray adjective played no role in the analysis, as confirmed by the concluding observation that, on remand, the Postmaster General could still try to show that mailing the letters at issue "amount[ed] to a violation of the statutes as herein construed." *Id.* at 111. Likewise, post-APA cases continue to rely on *McAnnulty* as support for granting non-statutory equitable relief in garden-variety statutory-interpretation disputes over the lawfulness of executive action. *See, e.g.*, *Harmon*, 355 U.S. at 582-83 (in holding that agency head considered impermissible factors when making certain personnel decisions, Supreme Court first construed the statute under which he acted to be coterminous with another statute and then construed latter statute narrowly); *Reich*, 74 F.3d at 1332-39 (in holding that Executive Order under Procurement Act conflicted with NLRA, D.C. Circuit engaged in eight-page analysis of the extent to which former statute's broad terms were implicitly narrowed by latter statute's specific terms and preemptive purposes).

So what about all the cases cited by the Government applying a heightened "*ultra vires*" standard? Like "jurisdiction," the term "*ultra vires*" has "too many[] meanings" in the law, *see Steel Co.*, 523 U.S. at 90, and the Government is engaged in semantic sleight-of-hand. As detailed below, it relies on a variety of cases involving different procedural contexts than this one.

First, the Government cites a case where the APA's sovereign-immunity waiver was unavailable and thus the plaintiff needed to rely on the fiction that a suit against a federal officer

for allegedly unlawful official acts was not a suit against the United States. *See Danos v. Jones*, 652 F.3d 577, 581-82 (5th Cir. 2011) (suit against members of judicial council, who were not officers of an "agency" covered by § 702, *see* 5 U.S.C. § 551(1)(B)). In that context, courts sometimes have construed the fiction narrowly by requiring that the officer's action lack any "colorable basis" in law before it will be "considered individual and not sovereign action[.]" *See Danos*, 652 F.3d at 583; *cf. Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 101 n.11 (1984) (suit trying to invoke analogous fiction against state official for violating state law). Even if that narrow construction were correct—*but see, e.g.*, *Alabama Rural Fire Ins. Co. v. Naylor*, 530 F.2d 1221, 1226 (5th Cir. 1976) (noting that Supreme Court's precedents only require violation of "statutory limitation" for officer to be stripped of sovereign immunity)—it would be irrelevant here because, as the Government itself concedes, § 702 waives sovereign immunity. *See supra* at 15-16. Sovereign immunity thus provides no justification for ratcheting up the merits standard under *McAnnulty*. *Cf. Apter*, 80 F.4th at 588 ("[a]ssuming without deciding" that higher standard applies even when § 702 waives immunity, since higher standard was satisfied regardless).

Second, the Government cites a slew of cases where, even though the substantive statute that was the source of the plaintiff's claim precluded judicial review, courts sometimes have held that Congress would not have wanted to preclude relief for egregious illegality.[5] None of those cases hold that the APA precludes non-statutory equitable relief for unlawful agency action, or

[5] *See Leedom v. Kyne*, 358 U.S. 184, 187-91 (1958) (NLRA implicitly precludes review of bargaining-unit determinations until they give rise to an unfair-labor-practice order); *Oestereich v. Selective Serv. Sys. Loc. Bd. No. 11*, 393 U.S. 233, 235-39 (1968) (Military Selective Service Act of 1967 expressly precludes judicial review of certain pre-induction actions); *Board of Governors of Fed. Rsrv. Sys. v. MCorp Fin., Inc.*, 502 U.S. 32, 42-44 (1991) (Financial Institutions Supervisory Act of 1966 expressly precludes review of certain actions by Federal Reserve Board); *Griffith v. FLRA*, 842 F.2d 487, 490-93 (D.C. Cir. 1988) (Civil Service Reform Act of 1978 has comprehensive remedial scheme that implicitly precludes alternative remedies); *Nyunt v. Chairman, Broadcasting Bd. of Governors*, 589 F.3d 445, 448-49 (D.C. Cir. 2009) (same); *cf. Fed. Exp.*, 39 F.4th at 763-66 (2018 Export Controls Act expressly precludes APA review but is silent about suit for non-statutory equitable relief).

that the APA's unavailability increases the standard for relief under *McAnnulty*. Those cases are thus all irrelevant here because the Government does not argue that *HIPAA* precludes Plaintiffs' claim for equitable relief. Nor could the Government plausibly make such an argument. Not a word in HIPAA purports to preclude covered entities from challenging HHS rules that misconstrue the IIHI definition.[6] Indeed, the Government concedes that Plaintiffs *can* bring a pre-enforcement challenge so long as the Revised Bulletin is final for APA purposes. *See* Defts. Br. 15, 27.[7]

The Government further errs in asserting that the availability of ordinary equitable relief in cases like this would leave "little reason for any plaintiff to rely on the APA" or "to comply with the limitations" imposed by the APA's finality requirement. *See* Defts. Br. 25. Where an agency acts within its statutory authority, the APA supplies additional substantive and procedural grounds to challenge the agency action—*e.g.*, requirements to provide a reasoned explanation and opportunity for public comment in some contexts—but only if it is "final." *See Apter*, 80 F.4th at 593. But where an agency acts "in *excess* of [its] express or implied powers," the APA's finality requirement does not require "one who has been injured by [the] act[ion]" to delay seeking the equitable relief that is "[g]enerally" available under *McAnnulty*. *See Harmon*, 355 U.S. at 581-82 (emphasis added). Contrary to the Government's suggestion, the APA does not supply "an

[6] Although HIPAA does provide a special judicial-review scheme for challenging the imposition of civil penalties on a particular covered entity, *see* 42 U.S.C. §§ 1320d-5(a)(2); 1320a-7a(e), that scheme does not preclude pre-enforcement challenges to HHS rules interpreting the IIHI definition. The text does not call for precluding these claims, and atextually extending the scheme that way would make no sense. Since entities who comply with such rules under the coercive threat of penalties will not be assessed any penalties, they must retain the means to directly challenge the agency's unlawful regulation of their conduct. *See, e.g.*, *Texas v. Brooks-LaSure*, No. 6:23-cv-161, 2023 WL 4304749, at *9 (E.D. Tex. June 30, 2023) (review scheme for denial of Medicaid funds did not preclude Texas from challenging CMS bulletin, because funds would not be denied "[i]f Texas abide[d] by the potentially unlawful Bulletin," and Texas was not required to "'bet the farm' and ignore the Bulletin" to "test[] its validity").

[7] For similar reasons, the Government goes far astray by invoking *American Airlines, Inc. v. Herman*, 176 F.3d 283, 286-94 (5th Cir. 1999), and *Exxon Chemicals*, 298 F.3d at 466-70. Those cases simply held that parties subject to an ongoing agency adjudication needed to exhaust their administrative appeals and could not collaterally attack interlocutory rulings in federal court.

adequate remedy at law" rendering equitable relief unwarranted. *See* Defts. Br. 25. The APA provides no money damages for past injuries caused by unlawful rules, only prospective relief like injunctions and declarations, *see* 5 U.S.C. §§ 702, 703; and it is patently inadequate to force Plaintiffs to wait to bring an APA challenge to a "final" civil-penalty order that will never happen because HHS's rule is chilling them from engaging in the proscribed conduct, *see supra* at 21 n.6.

In sum, where neither sovereign immunity nor statutory preclusion is at issue, there is no justification to heighten the standard under *McAnnulty* for enjoining unlawful agency action. After all, "for agencies charged with administering congressional statutes," "when they act improperly, no less than when they act beyond their jurisdiction, *what they do is ultra vires*," because "[b]oth their power to act and how they are to act [are] authoritatively prescribed by Congress." *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013) (emphasis added).

2. Declaratory relief. Federal courts also have the power to issue declaratory relief that a rule exceeds an agency's statutory authority, regardless of whether it is "final" under the APA. The Declaratory Judgment Act (DJA) authorizes this Court to "declare the rights and other legal relations of any interested party" "[i]n a case of actual controversy within its jurisdiction." 28 U.S.C. § 2201. Here, it is undisputed that there is an "actual controversy" between the parties, and that 28 U.S.C. § 1346(a)(2) confers original "jurisdiction" over this civil action against the United States. *See supra* at 14-16. Nor should there be any dispute that any lack of APA finality does not divest this Court of jurisdiction under § 1346(a)(2) to issue a declaratory judgment resolving the parties' controversy. *See supra* at 13-14. That should be the end of the analysis.

Lacking any basis in the DJA's text to argue that declaratory relief is unavailable here, the Government tries to manufacture an atextual limitation based on inapposite precedent. Invoking *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667 (1950), and its progeny, the Government

starts from the premise that the DJA "does not itself create an independent cause of action" to sue, and that it only "enlarge[s] the range of remedies available" in cases that otherwise fall within a federal court's jurisdiction. *See* Defts. Br. 26. The Government then leaps to the conclusion that "the independent cause of action required" does not exist because "Plaintiffs do not assert that HHS would be within its power to bring an enforcement action in federal court against them." *See id.* (cleaned up). The Government's argument is fundamentally flawed at every level.

Skelly Oil does not impose an atextual "independent cause of action" limitation on the DJA. Rather, it merely construed the DJA's textual requirement that the controversy must fall within the court's subject-matter "jurisdiction," by applying "the well-pleaded complaint rule" necessary to satisfy "federal-question jurisdiction" under 28 U.S.C. § 1331. *See Franchise Tax Bd. of Cal. v. Construction Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 15-16 (1983). In particular, the declaratory-judgment plaintiff there was preemptively "anticipat[ing]" a federal "defense" to its state-law "contract[]" suit, and the Court held that such "artful pleading" did not create federal jurisdiction over a contract claim "indubitably arising under State law." *Skelly Oil*, 339 U.S. at 672-74. It is crystal clear that the inquiry under *Skelly Oil* whether either party would have a non-declaratory federal cause of action applies only to DJA claims where jurisdiction rests *solely* on the federal-question statute. After all, *Skelly Oil* itself held that it "must reach the merits" of the DJA claim with respect to the parties between whom "there [was] diversity of citizenship." *Id.* at 674. With that proper understanding of *Skelly Oil* in mind, it becomes clear that there are three independent flaws with the Government's position that the DJA's availability turns on whether HHS could bring a civil enforcement action against Plaintiffs in federal court.

First, § 1346(a)(2) supplies subject-matter jurisdiction for a DJA claim that *the United States* has exceeded its authority under HIPAA, regardless of whether federal-question jurisdiction

exists under § 1331. Like the diversity of certain defendants in *Skelly Oil*, the presence of the United States as a defendant is sufficient to support jurisdiction over a DJA claim. The Fifth Circuit too has recognized that, independent of the nature of the claims asserted, the status of the parties can supply the jurisdiction necessary to grant declaratory relief under the DJA. *See In re B-727 Aircraft Serial No. 21010*, 272 F.3d 264, 270-75 (5th Cir. 2001) (holding that there was no jurisdiction over DJA claim brought *by* foreign ambassador, but only because the applicable jurisdictional statutes were limited to suits *against* ambassadors). The Government cites no precedent rejecting a DJA claim against the United States despite the existence of jurisdiction under § 1346(a)(2). In one of its cited cases, the Fifth Circuit upheld a DJA claim against the United States because federal-question jurisdiction *also* existed, given that the EEOC could bring a civil enforcement action against the declaratory-judgment plaintiffs. *See Braidwood Mgmt., Inc. v. EEOC*, 70 F.4th 914, 932-33 (5th Cir. 2023). And in the other, the Fifth Circuit rejected a DJA claim where the United States was not a party at all, and where certain local governments improperly attempted to invoke the DJA to obtain a determination of private parties' obligations under a *state law* despite the fact that state law itself denied them "a private right of action" to enforce the duty alleged. *See Harris Cnty. v. Merscorp Inc.*, 791 F.3d 545, 552-53 (5th Cir. 2015).

Second, even if the availability of a non-declaratory federal cause of action were a necessary predicate to invoking the DJA, *Plaintiffs* have such a cause of action, regardless of whether the Government does. As discussed, Plaintiffs may invoke this Court's jurisdiction to grant non-statutory equitable relief against unlawful agency action under *McAnnulty* and its progeny. *See supra* at 16-22. Because "injunctive relief is appropriate, it follows that declaratory relief may also be granted." *Ciudadanos Unidos de San Juan v. Hidalgo Cnty.*, 622 F.2d 807, 829 n.47 (5th Cir. 1980). Moreover, even accepting the Government's view that Plaintiffs fail to satisfy

some heightened "*ultra vires*" standard for non-statutory equitable relief, that at most would mean their request for an injunction fails *on the merits*. Any such judge-made standard modifying *McAnnulty* is necessarily a "claim-processing rule[]" that does not limit the "jurisdiction" of federal courts to award equitable relief, which "[o]nly Congress may determine." *Kontrick v. Ryan*, 540 U.S. 443, 452-54 (2004); *see Steel Co.*, 523 U.S. at 89. Thus, "'regardless of whether injunctive relief may be appropriate, federal declaratory relief is not precluded.'" *Anatol Zukerman & Charles Krause Reporting, LLC v. USPS*, 64 F.4th 1354, 1366 (D.C. Cir. 2023) (quoting *Steffel v. Thompson*, 415 U.S. 452, 475 (1974)).

Third, even if a non-declaratory federal cause of action had to be possessed by the Government, the United States has the power to bring a *criminal* prosecution to enforce HIPAA, regardless of whether HHS could bring a civil enforcement suit. In particular, HIPAA makes it a crime to knowingly and unlawfully disclose IIHI to another person. *See* 42 U.S.C. § 1320d-6. And DOJ has filed a brief for the United States taking the positions (1) that it is "plain" the Proscribed Combination "constitutes IIHI" with respect to "users who *are* visiting" health-related webpages "for their health care needs"; (2) that "it is beyond dispute that some individuals who visit these sorts of webpages *are* doing so in connection with their own health care needs"; and (3) that covered entities may not disclose the purported IIHI "to third-party vendors" of "tracking technologies." *See* Defts. Br. 30-31. So Plaintiffs are entitled to seek a declaratory judgment that, instead, such disclosure of the Proscribed Combination would not violate HIPAA. *See, e.g.*, *N.H. Lottery Comm'n v. Rosen*, 986 F.3d 38, 49-54 (1st Cir. 2021) (granting declaratory judgment that certain conduct did not violate federal criminal statute, notwithstanding that the government official who had expressed the contrary view was in DOJ's Office of Legal Counsel, not an actual prosecutor threatening the declaratory-judgment plaintiffs).

In sum, this Court has the power to grant declaratory relief. The Government cannot escape judicial review of the lawfulness of its interpretation of the IIHI definition. That would flout the "ordinar[y] presum[ption] that Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command." *See Bowen v. Michigan Acad. of Family Physicians*, 476 U.S. 667, 681 (1986).

II. THE GOVERNMENT HAS FORFEITED ANY MERITS DEFENSE OF THE ORIGINAL BULLETIN, WHICH WAS UNLAWFUL AND REMAINS SUBJECT TO INJUNCTIVE AND DECLARATORY RELIEF

After trying so hard to escape judicial review, when the Government eventually turns to the merits, it defends the Revised Bulletin, but *not* the Original Bulletin. *See* Defts. Br. 26. It buries in a footnote its justification for "generally address[ing] the Revised Bulletin" only: "[b]ecause the original Bulletin has been superseded," the Government asserts that "it can no longer be set aside or enjoined, as Plaintiffs originally requested." *See id.* at 3 n.2. That is false.

For starters, the injunctive relief that Plaintiffs actually requested was for this Court to enjoin Defendants "from enforcing against [them] *the rule in* the Bulletin that the Proscribed Combination is IIHI." Compl. at 21 (emphasis added). The fact that the challenged "language" in the Original Bulletin adopting the rule "was eliminated by the [agency]'s recent revisions" does not prevent this Court from "enjoining [future] enforcement" activities by Defendants based on that erroneous IIHI interpretation. *See Speech First, Inc. v. Fenves*, 979 F.3d 319, 327, 338 (5th Cir. 2020). Moreover, Plaintiffs also sought a "[d]eclaratory judgment that the Proscribed Combination does not constitute IIHI under the statutory and regulatory definition." Compl. at 21. That "declaratory relief is not precluded" "regardless of whether injunctive relief" remains warranted. *See Anatol Zukerman*, 64 F.4th at 1366. On both counts, it warrants repetition that the Government never argues that Plaintiffs' claims against the Original Bulletin are *moot*, and any such argument would be foreclosed by the voluntary-cessation doctrine. *See supra* at 14-15 & n.3.

Accordingly, the Government has forfeited any merits defense of the Original Bulletin. This Court could grant the requested relief on that basis alone, but resolving the merits would be almost as simple. The Government does not defend the Original Bulletin because it is plainly indefensible, and this Court need look no further than the Revised Bulletin to see why.

As demonstrated above, the Original Bulletin concluded that a "regulated entity is disclosing PHI to [a] tracking technology vendor, and thus the HIPAA rules apply," so long as (1) the technology "collect[s] an individual's email address and/or IP address when the individual visits" an Unauthenticated Public Webpage; and (2) the page allows the visitor "to search for available appointments with a health care provider" (or "addresses specific symptoms or health conditions"). AR 22; *see supra* at 7-8. But the Revised Bulletin itself says that the Original Bulletin was wrong to deem this Proscribed Combination alone to always be IIHI.

The Revised Bulletin admits that "the mere fact that an online tracking technology connects the IP address of a user's device (or other identifying information) with a visit to a webpage addressing specific health conditions or listing health care providers is not a sufficient combination of information to constitute IIHI…." AR 4. The Revised Bulletin also explains why that is so under the IIHI definition: "even if [such] information could be used to identify" the visitor, it does not, by itself, "relate[] to" the visitor's "past, present, or future health, health care, or payment for health care." AR 6; *see* 42 U.S.C. § 1320d(6). And the Revised Bulletin illustrates the point by giving the example of a "student … writing a term paper." AR 6.

The flaws with the Original Bulletin go far deeper than its improper coverage of students and others whose visits to a webpage are unrelated to their own health, as discussed below in connection with the Revised Bulletin. But that defect is enough to show that the Original Bulletin erred in adopting the rule that the Proscribed Combination alone is always IIHI. To repeat, even

assuming that the website metadata comprising the Proscribed Combination shows that the webpage owner "received" "information" revealing that an identifiable individual visited a health-related webpage, *that* information, by itself, is not "related" to the individual's own health, as the IIHI definition requires. The information the owner actually "received" does not show whether the individual visited the page because of something concerning his own health, rather than for any of countless other reasons; the metadata alone thus shows nothing about his own health.[8]

III. THE REVISED BULLETIN EXCEEDS HHS'S AUTHORITY UNDER HIPAA

Although HHS now recognizes that the Original Bulletin erred in treating the Proscribed Combination alone to always be IIHI, the agency did not solve the problem. The Revised Bulletin's gloss on the Proscribed Combination only requires that the identifiable individual's subjective reason for visiting the health-related page be related to his own health: "the mere fact that an online tracking technology connects the IP address of a user's device (or other identifying information) with a visit to a webpage addressing specific health conditions or listing health care providers is … a sufficient combination of information to constitute IIHI if the visit to the webpage is … related to" the individual's own health. AR 4 (double negative omitted); *accord* Defts. Br. 31 ("[I]dentifying information about users who *are* visiting the webpage for health care needs constitutes IIHI."). The Revised Bulletin provides examples to "make this distinction plain." *See* Defts. Br. 31-32. It contrasts two identifiable individuals who, for different reasons, "visited the

[8] The Government's amicus thus completely misses the point in devoting the bulk of her brief to arguing that IP addresses can be individually identifying in at least some circumstances. *See* Doe Br. 8-14. Plaintiffs' claim in this suit "assum[es] (without conceding)" that an IP address may satisfy the "identifies" clause of the IIHI definition, *see* Pltfs. Br. 3, focusing instead on Defendants' failure to properly apply the "relates to" clause. Moreover, amicus's fact-intensive discussion about IP addresses shows, if anything, that HHS's conclusory treatment of the topic is far too simplistic. *See* AR 4, 15 n.21, 20-21, 29-30 n.21. Indeed, contrary to amicus's position, courts have often held, in various contexts, that "an IP address is *not* personally identifiable" given how a user's "computer is assigned an IP address by the user's Internet service provider." *See, e.g.*, *Johnson v. Microsoft Corp.*, No. C06-0900, 2009 WL 1794400, at *3-4 (W.D. Wash. June 23, 2009) (emphasis added).

same webpage listing oncology services"—"a student … *for the purpose of* researching a term paper," and a cancer patient "*for the purpose of* seeking a second opinion on treatment options for their brain tumor." *See id.* at 12 (emphasis added; cleaned up). Based solely on this difference between the visitors' undisclosed subjective motives for visiting the page, the Revised Bulletin says that "collection and transmission of … information showing the[] visit" of the second individual, but not the first, "is a disclosure of PHI"—regardless of whether *any information revealing the visitor's motive* is disclosed to the page owner and collected by the online tools on the page. *See* AR 6; Defts. Br. 12, 30-31. And because "[c]ommon sense dictates that at least some users who visit these pages … are doing so … [for] reasons related to their own health care," *see* Defts. Br. 30, the change from the Original Bulletin to the Revised Bulletin is illusory. HHS has just gone from saying that disclosure of the Proscribed Combination always discloses IIHI to saying that it inevitably will disclose IIHI in at least some unidentifiable cases.

That fig leaf of a revision is still an erroneous interpretation of the IIHI definition. Webpage metadata merely showing that an identifiable individual visited a health-related webpage is not alone IIHI, as HHS itself now concedes. That information cannot become IIHI based solely on the visitor's subjective motive for visiting the page, which is not *information* that the Revised Bulletin requires the healthcare provider or third-party vendor to *receive* at all. The Government neither addresses this fundamental flaw with its new rule nor cites any authority supporting it. And every relevant principle of statutory interpretation cuts strongly against the Government's position.

A. HIPAA's Text Dictates That The Revised Bulletin Is Unlawful

The core defect in the Revised Bulletin is that it disregards a critical textual element of the IIHI definition: the "information" that "relates to" a reasonably identifiable individual's health, healthcare, or payment for healthcare must be "created or received" by the covered entity. 42 U.S.C. § 1320d(6). Yet in the Revised Bulletin, the only "information" that the covered entity

must "receive" to trigger the Proscribed Combination is metadata showing that an identifiable individual visited a health-related webpage. AR 6. And HHS has conceded that this information does *not alone* "relate to" the individual's health—it concerns the "mere fact" of the visit, AR 4, not whether there is a health-related reason for the visit, AR 6.

HHS contends, however, that the same metadata showing the mere fact of the visit becomes "related to" the identifiable individual's health "if the visit" itself was related that way. AR 6; *accord* Defts. Br. 31-32. But the Revised Bulletin does not require a webpage owner to have *received* any information regarding a visitor's subjective reason for visiting the webpage.

The Revised Bulletin thus rewrites the IIHI definition, by focusing on whether the individual's *motive* for the visit was "relate[d] to" his health, not whether the "information" actually "received" by the covered entity about the visit "relate[d] to" his health. 42 U.S.C. § 1320d(6). A visitor's subjective purposes for visiting the page are not "received" by the page owner or disclosed to the third-party technology vendor, and so such undisclosed motives cannot transform webpage metadata into IIHI when it otherwise would not be. While the phrase "relates to" is a broad term, *see* Defts. Br. 27, it cannot mean that whether metadata is "information" "received" by a covered entity that "relates to" an individual's health turns on an extrinsic fact (the reason for the visit) that is not "received" by the covered entity at all. That reading is far "too tenuous" and would push the term past "the furthest stretch of its indeterminacy." *See* Pltfs. Br. 20 (citing cases warning against overbroad readings of "relates to").

The structure of the IIHI definition underscores the agency's error. As previously set forth, the definition has two key clauses—the "identifies" clause and the "relates to" clause. *See* Pltfs. Br. 19 (block-quoting clauses). For the "identifies" clause, Congress said that the "information" "received" by the covered entity need only provide "*a reasonable basis* to believe that the

information *can be used* to identify the individual." 42 U.S.C. § 1320d(6)(B) (emphasis added). That does not require the information to identify the individual, and it focuses on whether the information can reasonably be used to identify the individual. In stark contrast, for the "relates to" clause, Congress said that the "information" "received" by the covered entity must itself "relate[] to" the individual's health. *Id*. Congress did not even cover information that provides "a reasonable basis to believe" it "relates to" the individual's health—much less information that purportedly "relates to" an individual's health based entirely on the individual's subjective beliefs, even when the covered entity would have *no basis whatsoever* to know those beliefs. This Court should not countenance HHS's attempt to rewrite the "relates to" clause as a laxer (and absurd) version of the "identifies" clause. *See* Pltfs. Br. 19-20 (citing case about interpreting companion provisions in light of their differences).

To be clear, Plaintiffs' position in this suit is not, as the Government straw-mans it, that "tracking technologies used on unauthenticated webpages 'can never' provide a reasonable basis to identify 'the individual' to whose health care needs the information 'relates.'" *See* Defts. Br. 30. Rather, what "can never" be sufficient under the IIHI definition is the Original Bulletin's reliance on receiving "[t]he combination of" *only* the "two pieces of information" that (1) an identifiable individual (2) visited a covered entity's health-related webpage. *See* Pltfs. Br. 17. And that conclusion holds true even adding the Revised Bulletin's reliance on a third piece of information that the covered entity does not receive—namely, the fact that the individual's subjective reason for visiting the page happened to be related to his own health.

Accordingly, a very different question would have been presented if HHS had limited the Revised Bulletin to situations where the individual provided his health-related reason on the webpage (*e.g.*, by identifying symptoms as his own or booking an appointment for himself with a

provider) and this information was collected and transmitted by the online technology. Although the Government's brief repeatedly suggests scenarios like that, *see, e.g.,* Defts. Br. 2, 17, 28, it is "a red herring," *id.* at 30, as the Revised Bulletin does not require the receipt of such information. Look again at the contrast between the student and the cancer patient visiting the oncology-services page: the Revised Bulletin does not say that the technology collected any objective information that showed the differing reasons for the visits, instead distinguishing between the visitors based *solely* on their subjective motives for the visits. *See* AR 6. This is even clearer in the "Ms. Doe" hypothetical in the Government's brief. Even if Ms. Doe "clicks on a link to a page entitled 'Find a Doctor,' enters 'oncologist' into the search bar, and then through a drop-down menu of conditions filters for particular oncologists that specialize in reviewing abnormal mammograms," none of that provides the covered entity or the third-party technology vendor with any "information" that her visit relates to her own health. *See* Defts. Br. 29. Indeed, all of that is entirely consistent with Ms. Doe being a public-health researcher, friend of a cancer patient, etc.

In short, HHS did not attempt to limit the Revised Bulletin to situations where online technologies collect information showing that an identifiable individual visited a health-related page because of something about her own health. Instead, it deemed sufficient that the individual's undisclosed motive for the visit was related to her own health. Yet it made no effort to reconcile treating that extrinsic fact as dispositive with the "received" element of the IIHI definition.

B. HIPAA's Context Confirms That The Revised Bulletin Is Unlawful

The Revised Bulletin's flouting of the text becomes even more inexplicable when the words of the IIHI definition are "read in their context and with a view to their place in the overall statutory scheme." *Ali v. Barr*, 951 F.3d 275, 280 (5th Cir. 2020). For three reasons, HHS failed in its "role to make sense rather than nonsense out of the *corpus juris*." *Id.*

First, the Revised Bulletin regulates the collection and transmission of information that does not remotely implicate HIPAA's purposes. As HHS has explained, the statute and its implementing regulations aim to "assure that individuals' health information is properly protected." *See* Pltfs. Br. 1; *accord* Defts. Br. 1 (summarizing HIPAA's purpose as "ensur[ing] that Americans can seek health care without fearing that their sensitive health information will be made public"). But, as HHS concedes, information showing the mere fact that an identifiable individual visited a health-related webpage poses no cause for concern. That information alone reveals nothing about the reason the individual visited the page, whether related to his own health or for any of countless other reasons that individuals may visit such pages. And while some individuals, of course, may in fact have visited for reasons related to their health, that information remains "protected" in their own heads, because neither the covered entity nor the third-party technology vendor knows it. The use of online tools on public webpages is thus very different than on user-authenticated patient portals, which is why Plaintiffs' suit is limited to the former. *See* Pltfs. Br. 6 n.2. Again, going back to Ms. Doe, the online technology obtains no information showing whether she is a cancer patient, a researcher, a patient's friend, or someone else, so there is no private "health information" in the mere metadata of her visit that must be protected from disclosure. In short, rather than "interpret[ing] [HIPAA] in a manner that comports with [its] policies," the Revised Bulletin "contribute[s] nothing to th[ose] policies." *See W. Airlines, Inc. v. Bd. of Equalization*, 480 U.S. 123, 134 (1987).

Second, the Revised Bulletin's rule is concededly unworkable. Precisely because covered entities do not know the private reason why any given user chooses to visit their webpages, they cannot know which records of a visit are IIHI under the modified Proscribed Combination and which are not. With considerable understatement, the Government acknowledges the

"difficult[y]" of complying with the Revised Bulletin, given that "at least some users" visit for reasons related to their own health, but regulated entities cannot "disaggregate" which users are which. *See* Defts. Br. 30-31. The Government's incredible response, though, is that "it may be prudent for regulated entities to prevent disclosures of *non-IIHI* if that is the only way to ensure that they are not disclosing PHI" as (mis)interpreted in the Revised Bulletin. *See id.* at 31 (emphasis added). In other words, even though HHS admits that the Original Bulletin was wrong to decree that the Proscribed Combination is always IIHI, the Revised Bulletin adopted a meaningless tweak that leads to the same erroneous result. Namely, the Government recognizes that, under its view, the Proscribed Combination will *inevitably* contain at least some IIHI, and thus will need to be treated *as if* it were *always* IIHI because it is *impossible* to identify the conceded non-IIHI. While the Government dismisses this result as a "practical" problem, *see id.*, it vividly illustrates the legal flaw in the agency's interpretation. The "information" that is essential to the IIHI classification must actually be "received" by the covered entity. 42 U.S.C. § 1320d(6). This Court should reject HHS's construction of the statute, which will "prove exceedingly difficult to apply" as it invites an "indeterminable line-drawing exercise" turning on the unrevealed motives of third parties. *See Stokeling v. United States*, 139 S. Ct. 544, 554 (2019).

Third, the Revised Bulletin dismisses the harms caused by its overbroad IIHI interpretation. As HHS used to recognize, HIPAA and its implementing regulations "strike[] a balance" by carefully limiting the scope of IIHI and thereby "allow[ing] the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being." *See* Pltfs. Br. 1-2. To be sure, the Revised Bulletin pays lip service to the fact that "insights" from online technologies "could be used in beneficial ways to help improve care or the patient experience, improve the utility of webpages and apps, or allocate resources." AR 3. But the

Revised Bulletin deprives covered entities of those insights by gratuitously expanding the scope of IIHI to reach information that reveals nothing about an individual's own health status, effectively including even information that HHS concedes is *not* IIHI.

It is no answer to any of this for the Government to stress that the Revised Bulletin does not categorically prohibit the use of online technologies because it is theoretically possible covered entities could enter into business associate agreements with third-party technology vendors or de-identification vendors. *See* Defts. Br. 33-34. As Plaintiffs have explained, the agency's rule that the Proscribed Combination constitutes IIHI is actively deterring covered entities from using valuable online technologies. Among other challenges, major third-party vendors will not agree to business associate agreements and work-arounds like deidentification are costly and less effective. *See* Pltfs. SJ Appx. 26-28, 36-37, 41-43. Plaintiffs should not have to suffer these burdens and harms that result from the Revised Bulletin's extra-statutory rule.

C. HHS's Inconsistent Practice Confirms That The Revised Bulletin Is Unlawful

HHS's construction of the IIHI definition is also "unpersuasive" because it lacks "consistency" with the agency's other "pronouncements," including ones both "earlier and later" and even contemporaneously. *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 159 (2012). Three inconsistencies are particularly significant here.

First, the Revised Bulletin is internally inconsistent. Like the Original Bulletin, the Revised Bulletin states that, even if online technology collects metadata showing that an identifiable visitor visited a particular hospital webpage, that "would not involve a disclosure of an individual's PHI" if the page contained *only general information* such as "visiting hours," because the technology would "not have access to information about" the individual's own health. AR 6; *see* AR 22. While that is certainly true, it is equally true even if the webpage concerns specific health conditions or healthcare providers, so long as the technology likewise does "not

have access to information" about whether the individual is visiting the page for health-related reasons or non-health-related reasons. Put differently, under the Revised Bulletin, the individual's subjective motive for visiting the page is the decisive factor that determines whether metadata showing an identifiable individual visited the page is information "related to" the individual's own health; but if that subjective motive is what makes the metadata information "related to" the individual's own health, it is not evident why the objective information on the page even matters.

To make the point more concrete, consider again the Revised Bulletin's cancer patient or the Government's Ms. Doe. If the metadata showing their visits to the oncology-services webpage is information "related to" their own health simply because the subjective motive for their visits related to their own health, then parallel logic would imply that metadata showing their visits to generic webpages addressing topics like "visiting hours" *also* is information "related to" their own health, so long as those visits likewise subjectively related to their own health (*e.g.*, because they wanted to find out what times their family members could come see them after a procedure). For both types of webpages, the subjective reason for the visit is health-related, but the metadata received shows the mere fact of the visit, not the reason that would make such information health-related or not. Of course, Plaintiffs are pleased that HHS did not follow its illogical path to the even more absurd result that the IIHI definition reaches metadata for even generic hospital webpages based simply on the subjective intent of visitors to such pages. But the agency's choice not to do so confirms that it should not have gone down this path at all—an individual's motive for visiting a webpage is irrelevant under the IIHI definition unless "information" of that motive is also "received" by the online tool. 42 U.S.C. § 1320d(6).

Second, the Revised Bulletin is inconsistent with prior HHS guidance. Just last year, HHS told hospitals that, while they must bar media personnel from "treatment or other areas … where

patients' PHI will be accessible," they may allow them in areas "that are otherwise generally accessible to the public, which may include public waiting areas or areas where the public enters or exists the facility." HHS, *Can health care providers invite or arrange for members of the media, including film crews, to enter treatment areas of their facilities without prior written authorization?* (Jan. 9, 2023), https://perma.cc/M4W6-NBA7. Of course, many of the identifiable individuals captured by cameras in areas like a hospital's garages and lobbies are actually patients who visit those areas for reasons related to their own health—namely, en route to or from treatment or similar areas. Yet HHS correctly recognized that no IIHI is created or received because the cameras cannot capture a patient's subjective reason for visiting the public areas, and that it is not until a patient enters treatment or similar areas that information related to the individual's own health is created or received.

The same logic applies to metadata showing the mere fact of a visit to an Unauthenticated Public Webpage, rather than to a patient portal. Indeed, it applies *a fortiori*. Cameras in public areas of a hospital are far more likely to collect information related to the health of an identifiable individual than online technologies collecting mere metadata information from public webpages.

Third, and most jarringly, the Revised Bulletin outlaws the undisputed current practices of an HHS sub-component and other federal agencies. As Plaintiffs have explained, CMS and other HIPAA-covered agencies operate Unauthenticated Public Webpages addressing specific health conditions and healthcare providers, and judicially noticeable information shows that third-party technologies collecting IP addresses are present on those pages. *See* Pltfs. Br. 9-10. As it is "beyond dispute that some individuals who visit these sorts of webpages *are* doing so in connection with their own health care needs," *see* Defts. Br. 30, those federal agencies are necessarily collecting and transmitting IIHI under the Revised Bulletin.

HHS entirely ignored this fact in the Revised Bulletin, and the Government's brief does not dispute it. *See id.* at 34-35. Nor does the Government suggest that these agencies permissibly collect and transmit the purported IIHI pursuant to business associate agreements, deidentification measures, or anything else. Instead, the Government imperiously proclaims that "the Revised Bulletin reminds [the other agencies] to protect that information consistent with the requirements of the HIPAA Rules, just as it does for regulated entities outside of the federal government." *See id.* at 35. Somehow, even a sub-component of HHS failed to receive this "reminder," as CMS still engages in the conduct proscribed by the Revised Bulletin. All of this shows that regulated entities inside *and* outside the government have been blindsided by HHS's novel position. *See supra* at 11. And it thus further confirms that Defendants are the only ones that need a "reminder" about the IIHI definition's proper scope, which evidently this Court alone can provide.

D. Judicial Precedent Confirms That The Revised Bulletin Is Unlawful

The Revised Bulletin's rule is also contrary to the federal caselaw holding that the "type of metadata" at issue "does not in the least bit fit into th[e] category" of information the IIHI definition covers. *Kurowski v. Rush Sys. for Health*, No. 22 C 5380, 2023 WL 4707184, at *4 (N.D. Ill. July 24, 2023); *see* Pltfs. Br. 21 (citing cases). In reasoning that such "information … cannot, in and of itself, reveal details of an individual's health status or medical history," those courts clearly foreclosed reliance on users' subjective motives that likewise are not "reveal[ed]" in the "information" actually received. *Smith v. Facebook, Inc.*, 745 F. App'x 8, 9 (9th Cir. 2018), *aff'g* 262 F. Supp. 3d 943, 954-55 (N.D. Cal. 2017). Tellingly, even when one such court recently denied a motion to dismiss an amended complaint, it still rejected HHS's misinterpretation of HIPAA. *Kurowski v. Rush Sys. for Health*, No. 22 C 5380, 2023 WL 8544084, at *2 (N.D. Ill. Dec. 11, 2023). Instead, it relied on (disputed) allegations that online tools had transmitted the plaintiff's patient status, communications within the patient portal, and details about her personal

physician, *see id.* at *1, 3—the type of identifiable and health-related information actually "received" by the covered entity that HHS inexplicably chose not to require, *see supra* at 31-32.

The Government's sole response to these cases is that "[t]he Court should decline to follow them" on the ground that they "are all non-binding and engage only in a cursory analysis of the statutory language." *See* Defts. Br. 34-35. That is more than a little rich coming from the Government, which has yet to provide any textual analysis whatsoever of how a webpage user's subjective reason for visiting a webpage is the decisive factor under a statutory definition limited to "information" "received" by the covered entity. Unsurprisingly, the Government fails to cite any authority actually supporting its atextual position. Rather than basing an IIHI finding on the plaintiffs' private motives for visiting the providers' webpages, one of the Government's cases involved a patient-portal page and disclosure of patient status, *see In re Meta Pixel Healthcare Litig.*, 647 F. Supp. 3d 778, 791-92 (N.D. Cal. 2022), and the other relied on the Original Bulletin's since-repudiated categorical rule against the Proscribed Combination, *see Cousin v. Sharp Healthcare*, No. 22-cv-2040, 2023 WL 8007350, at *2-3 (S.D. Cal. Nov. 17, 2023).

E. Constitutional-Avoidance Principles Confirm That The Revised Bulletin Is Unlawful

Finally, the serious constitutional concerns raised by HHS's expansive interpretation of the IIHI definition independently require rejecting that interpretation. *See* Pltfs. Br. 21-23. The Government's rejoinders do not pass the straight-face test.

The Government first insists, audaciously, that "[t]here is no statutory ambiguity" and that the IIHI definition purportedly *compels* the interpretation adopted in the Revised Bulletin. *See* Defts. Br. 35. But the Original Bulletin adopted a different and concededly erroneous interpretation, and the Revised Bulletin suffers from the flaws identified above. Thus, if anything, the statute forecloses HHS's rule and definitely does not require it.

The Government next asserts that its interpretation of the IIHI definition is subject at most to the intermediate-scrutiny standard governing commercial-speech restrictions. *See* Defts. Br. 35-36. But Supreme Court "precedents define commercial speech as 'speech that does no more than propose a commercial transaction,' and the [hospitals'] speech in question in this case does much more than that." *Harris v. Quinn*, 573 U.S. 616, 648 (2014) (citation omitted). HHS's expansive reading of the IIHI definition restricts the dissemination of information that Plaintiffs use to improve the operation of the publicly accessible webpages through which they communicate about "critical healthcare information" with *all* members of "the communities they serve," not just current and prospective patients. Pltfs. SJ Appx. 24. Community members visit such pages for a variety of reasons, such as to watch "educational videos about health conditions" or treatments. *See, e.g.*, *id.* at 27. In fact, the Surgeon General—himself an HHS official—has recognized this, explaining that "hospital systems can work with community members to develop localized public health messages" to combat "health misinformation." *See* V. Murthy, *Confronting Health Misinformation* 10 (2021), https://perma.cc/YD2V-4QJE. This is the type of "direct comment[] on public issues" for which companies "enjoy the full panoply of First Amendment protections." *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 562 n.5 (1980). Anyway, just as in *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), "the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied." *Id.* at 571.

The Government last claims that its interpretation of the IIHI definition survives constitutional scrutiny because it is reasonably tailored to important privacy interests. *See* Defts. Br. 36-38. But as discussed above, the agency's rule concerning the Proscribed Combination is completely untethered from any legitimate privacy interest. Under the Revised Bulletin, the information that is actually collected and transmitted is not itself sensitive health information (the

metadata showing the mere fact that an identifiable individual visited a health-related page, but not the reason for the visit), and the information that might actually be sensitive health information is not collected and transmitted at all (whether the individual's reason for visiting the page was related to his own health). *See supra* at 33. Indeed, the Government admits that the Revised Bulletin will even effectively restrict the disclosure of "non-IIHI" when an identifiable individual visits a health-related page for unknown reasons that, in fact, are *unrelated* to his own health. *See supra* at 33-34. That, in itself, refutes the reasonableness of the tailoring. Consequently, the purported privacy interest here is far *weaker* than the privacy interest in pharmacy-prescriber information that *Sorrell rejected* as inadequately tailored simply because the law at issue was under-inclusive. *See* Pltfs. Br. 22-23. Ignoring that point, the Government fixates on the fact that *Sorrell* suggested HIPAA was a reasonably tailored privacy law, 564 U.S. at 573, even though that says nothing about whether HHS's sweeping misinterpretation of HIPAA is reasonably tailored.

Having said all that, for purposes of the constitutional-avoidance canon, the question is not whether HHS's interpretation would ultimately survive constitutional scrutiny, but whether there are at least "serious … doubts" that it may not. *See* Pltfs. Br. 23. That low threshold is easily surpassed here. For that reason and all the others, the Revised Bulletin exceeds HHS's authority under HIPAA by adopting the rule that the Proscribed Combination is IIHI so long as the identifiable individual visited the health-related webpage because of his own health.

IV. HHS VIOLATED THE APA IN PROMULGATING THE REVISED BULLETIN

Even setting aside that the Original Bulletin exceeded HHS's statutory authority, it offered arbitrary-and-capricious reasoning and failed to undergo notice-and-comment rulemaking. HHS effectively proved Plaintiffs' point by revising the Original Bulletin shortly after this suit was filed in an (unsuccessful) effort to patch up the legal errors we identified. *See* Part II, *supra*. HHS's shoddy reasoning in the Original Bulletin overlooked obvious flaws with its rule against the

Proscribed Combination, and that illustrates why the regulated community should have had an opportunity to raise concerns with the agency before the rule was issued.

Remarkably, the Revised Bulletin is even more flawed than its predecessor in these respects. The Revised Bulletin still fails to provide any reasoned consideration of the key legal and policy questions raised by the agency's modified version of the Proscribed Combination, and that failure is especially egregious in light of the concerns surfaced through this litigation. Likewise, it is crystal clear that the Revised Bulletin was required to go through the notice-and-comment process, as the agency by then knew full well the significant effect on private interests that its new legal mandate is having.

A. The Revised Rule's Reasoning Is Even More Arbitrary And Capricious

The APA requires that an agency provide a reasoned analysis of the significant legal and policy questions implicated by its action. *See* Pltfs. Br. 27-28. Like the Original Bulletin, the Revised Bulletin falls far short in many important ways.

First, and "most obvious[ly]," the Revised Bulletin provides "*no* explanation whatsoever" on the key interpretive issue. *Clarke v. CFTC*, 74 F.4th 627, 641 (5th Cir. 2023). It offers no textual or other analysis of how "information" that is concededly not IIHI (metadata showing the mere fact that an identifiable individual visited a health-related webpage) somehow becomes IIHI based on an extrinsic fact (the individual's subjective reason for visiting the page) that the Revised Bulletin does not require covered entities to have "received" at all. *See* 42 U.S.C. § 1320d(6); Part III.A, *supra*. Even if that position were somehow "consistent with the statutory language," *see* Defts. Br. 39, it certainly is not *compelled* by that language. Yet HHS did not provide a shred of reasoning to justify its interpretive choice. Nor did it even "display awareness" that it was making a choice. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). This is much worse

than a "decision of less than ideal clarity," *see* Defts. Br. 38 (cleaned up); it is an *ipse dixit* "result" devoid of "*reasoning* for that result," *Clarke*, 74 F.4th at 641.

Second, the need for HHS to explain itself was acute. As the agency's counsel candidly concedes, adopting an IIHI interpretation that turns on the unknown (and unknowable) beliefs of third parties will have the "practical consequence" of coercing covered entities not to disclose even metadata that HHS admits *is* "non-IIHI," simply because there is no way to identify it as such. *See* Defts. Br. 31. That the agency itself "neither acknowledged nor explained" that its rule operates in this "nonsensical and unworkable" manner "is a telltale sign of arbitrary and capricious agency action." *Everport Terminal Servs., Inc. v. NLRB*, 47 F.4th 782, 794 (D.C. Cir. 2022).

Third, the Revised Bulletin suffers from multiple "unexplained inconsistenc[ies]." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016). Perhaps most importantly, HHS's treatment of (1) visits to health-related webpages is irreconcilable with its treatment of (2) visits to generic webpages and to public areas in or around a hospital. For category (2), information showing the mere fact of the visit is *not* "related to" the individual's health, and that is so regardless of the individual's reason for the visit; by contrast, for category (1), information showing the mere fact of the visit is "related to" the individual's health if, but only if, the individual had a health-related reason for the visit. *See supra* at 35-37. Although the agency's counsel will inevitably try in their reply brief to offer "*post hoc* justifications" for this evident incongruity, that will come too late because the agency itself was required to provide a "contemporaneous explanation[]" reconciling its warring positions. *DHS v. Regents of Univ. of Calif.*, 140 S. Ct. 1891, 1909 (2020).

Likewise, it appears that CMS and other HIPAA-covered federal agencies are necessarily violating the Revised Bulletin on their own webpages that collect the Proscribed Combination from "at least some" users who are visiting the pages for reasons related to their own health. *See*

supra at 37-38. As the filings in this case squarely raised the issue, HHS was obligated to explain either (1) why those agencies somehow are not violating the Revised Bulletin, or (2) why HHS is adopting an interpretation of HIPAA so strained that even its sub-components and sister agencies have failed to grasp this lurking implication of the statute. Contrary to the Government's suggestion (*see* Defts. Br. 39), what HHS was not permitted to do is taken an "ostrich-like approach" in which it simply "declined to engage with" the problem. *Env't Def. Fund v. FERC*, 2 F.4th 953, 975 (D.C. Cir. 2021).

Finally, the Revised Bulletin "failed adequately to substantiate[] the rule's benefits and costs" and then demonstrate that the benefits obtained "bear a rational relationship" to the costs imposed. *Chamber of Commerce of U.S. v. SEC*, 85 F.4th 760, 777 (5th Cir. 2023). The Government objects that "no statutory provision require[s] that sort of cost-benefit analysis for every agency action," *see* Defts. Br. 39, but *Chamber of Commerce* relied on the APA's general "arbitrary and capricious" requirement, not a matter-specific statute. *See* 85 F.4th at 777 & n.23; *see also Regents*, 140 S. Ct. at 1913-15 (holding that APA required agency, even when rescinding non-enforcement policy that conferred no substantive rights and that government believed lacked statutory authority, "to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns"). Moreover, such analysis is especially warranted under HIPAA, which the Government itself emphasizes "struck" a "balance" between "privacy benefits" and the speech "costs" of restricting information. *See* Defts. Br. 39. It thus was imperative for HHS, when interpreting the scope of the IIHI definition, to weigh the relative benefits and costs in light of that statutory balance.

Yet HHS completely failed to do so (as does the Government in its brief, *see* Defts. Br. 39-40). The agency ignored that the privacy benefits of its new rule are non-existent because this

expansion of the IIHI definition "protects" information that reveals nothing about an individual's own health status, effectively including even information that the agency concedes is *not* IIHI. *See supra* at 33-34. And conversely, the agency gave no meaningful weight to the public-health harms that flow from restricting the use of information that hospitals rely upon to strengthen the utility and functionality of webpages through which they communicate vital public-health information to the communities they serve. *See supra* at 34-35; Pltfs. Br. 8-11. Indeed, the administrative record reveals that, before issuing the Original Bulletin, HHS never consulted with the regulated community about the new rule's potential problems or otherwise considered any evidence of the beneficial uses of the information it was restricting, *see* AR Index at 2-8; likewise, before issuing the Revised Bulletin, HHS gave only minimal consideration to these issues—as exemplified by the shocking fact that the agency does not appear to have even reviewed the declarations supplied by Plaintiffs attesting to the real-world harms caused by the Original Bulletin, *see id.* at 1-2. This final insult, when added on top of all the injurious reasoning set forth above, "is the epitome of arbitrary and capricious action." *Clarke*, 74 F.4th at 641.

B. The Revised Rule Even More Clearly Needed To Go Through The Notice-And-Comment Process

At the very least, HHS was required to provide the public with notice and opportunity to comment on the Revised Bulletin, as its new legal mandate significantly affects private interests. *See* Pltfs. Br. 30-32. Neither of the Government's arguments for spurning that process has merit.

The Government initially suggests that the Revised Bulletin is a mere "policy statement" that advises how HHS "proposes to exercise a discretionary power." *See* Defts. Br. 41-42. To the contrary, the Revised Bulletin adopts a definitive interpretation of the IIHI definition that governs the scope of covered entities' duties under HIPAA. For the same reasons that this coercive new rule backed by civil penalties is final for APA review, *see* Part I.A, *supra*, it plainly imposes

"obligations" and deprives HHS staff of any "discretion" to adopt a different interpretation of the IIHI definition. *See Texas v. United States*, 809 F.3d 134, 171 (5th Cir. 2015). This is an *a fortiori* case compared to the mere "evidentiary standard" that the Fifth Circuit held was "a substantive rule" because it "affected the rights" of regulatory applicants. *RJ Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 193-94 (5th Cir. 2023). Tellingly, the Government cites no case deeming an agency rule that adopts a novel interpretation of private parties' statutory duties to be a policy statement.

The Government quickly falls back to the position that the Revised Bulletin is a mere "interpretive rule" that advises "the public of the agency's construction" of the IIHI definition. *See* Defts. Br. 42-43. But while fixating on some of the subsidiary factors that *Mock v. Garland*, 75 F.4th 563, 579-80 (5th Cir. 2023), considered in distinguishing between interpretive rules and legislative rules, the Government has basically nothing to say about whether the Revised Bulletin will have "significant effects on private interests," *id.* at 580. That is revealing, as *Mock* identified this factor as the "primary means" for "determin[ing] whether a rule is of the type Congress thought appropriate for public participation." *Id.* at 581.

The Government's sole response is that all such effects "flow from the HIPAA Rules' preexisting requirements." *See* Defts. Br. 43-44. But that is the precise argument made and rejected in *Mock* itself. There, an agency likewise claimed that the conduct proscribed by its new rule was "always unlawful," and that a court adjudicating an enforcement action "would determine whether the statute—not the [r]ule—covered the conduct." 75 F.4th at 582. The Fifth Circuit rejected the argument as "too clever by half" and "flatly unpersuasive given the history of [agency] regulation and action." *Id.* By adopting a novel interpretation of the statutory language that radically departed from the previous understanding shared by the agency and the regulated community, the agency was trying to "directly govern[] the conduct of members of the public,

affecting individual rights and obligations," which was likewise why *Mock*'s "speak with the force of law" factor was also satisfied. *See id.* at 580-51; *see also* Pltfs. Br. 32-33 (citing more cases focusing on whether agency has adopted novel statutory interpretation that alters private behavior).

Here, the Government does not and cannot dispute that the agency's novel interpretation of the IIHI definition is having the same type of effects, which is unequivocally proven by covered entities' response to the Original Bulletin. *See supra* at 11, 14. As in *Mock*, "the extraordinary implication[]" of the Government's position is that thousands of covered entities—including federal agencies—have been clearly violating HIPAA "the entire time" they used commonplace third-party technologies on their public webpages. 75 F.4th at 582. That is utterly implausible, confirming that "[t]he character of the rule is legislative." *Id.* At a minimum, therefore, HHS was required to provide the public an opportunity to raise concerns with the Revised Bulletin before unleashing its harmful impacts on covered entities and the communities they serve.

V. THIS COURT SHOULD GRANT ALL OF THE RELIEF PLAINTIFFS REQUESTED

The Government acknowledges that, if this Court concludes that it has jurisdiction and that Plaintiffs prevail on their claims, it at the very least should grant a declaratory judgment. *See* Defts. Br. 44. And the Government's arguments opposing any further relief are misguided.

To begin, the Government is incorrect that Plaintiffs have not "attempted to make the traditional showing required for the extraordinary remedy of injunctive relief." *See id.*; *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (permanent injunction requires showing (1) "irreparable injury"; (2) "remedies available at law … are inadequate"; (3) "balance of hardships between [parties]"; and (4) "public interest"). Although an injunction is not "granted as a matter of course," *see* Defts. Br. 44, it is plainly warranted in a case like this for essentially the same reasons that Plaintiffs have "clearly carried th[eir] burden of persuasion" (*id.*) on standing and the merits. *First*, it is well established that "the 'chilling effect' on a plaintiff's conduct that arises

from the threat of … civil penalties [is] sufficient to establish irreparable harm." *VanDerStok v. Garland*, 633 F. Supp. 3d 847, 856-57 (N.D. Tex. 2022) (citing cases; cleaned up); *see* Pltfs. Br. 12 (citing additional cases so holding in context of standing, which Government has not even contested). *Second*, the traditional legal remedy of money damages is inadequate here because "federal agencies generally enjoy sovereign immunity for any monetary damages," as the Government does not disavow. *Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021). *Third* and *fourth*, "there is generally no public interest in the perpetuation of unlawful agency action." *Texas v. Biden*, 10 F.4th 538, 560 (5th Cir. 2021) (per curiam); *see Nken v. Holder*, 556 U.S. 418, 435 (2009) ("public interest" and "harm" to the defendant "merge when the Government is the [defendant]"). To be sure, the Government raises a concern about "preventing the impermissible disclosure of PHI and the resulting loss of privacy for individuals." *See* Defts. Br. 45. But success on Plaintiffs' statutory-authority claim would mean the Proscribed Combination is *not* PHI at all; and success on their APA claims would trigger the Supreme Court's remedial admonition that "our system does not permit agencies to act unlawfully even in pursuit of desirable ends," *Alabama Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2490 (2021).

The Government's remedial objection thus reduces to a single point—that an injunction is unwarranted because "a declaratory judgment would be []sufficient to redress [Plaintiffs'] injuries." *See* Defts. Br. 44. This Court and others, however, routinely grant *both* declaratory and injunctive relief against federal officials. *See, e.g.*, *Nuziard v. Minority Bus. Dev. Agency*, No. 4:23-cv-278, --- F. Supp. 3d ----, 2024 WL 965299, at *43-44 (N.D. Tex. Mar. 5, 2024). And here, there are concrete reasons to doubt the Government's suggestion that a declaratory judgment alone would render an injunction unnecessary. *First*, given the post-suit "timing" of HHS's adoption of the Revised Bulletin, there is reason to be "suspicious" that the agency will comply with

declaratory relief, rather than trying to weasel around it based on more immaterial modifications, free from any threat of contempt sanctions. *Cf. Speech First*, 979 F.3d at 329. *Second*, the Government's own brief suggests that HHS may *not* comply with a declaratory judgment, affirmatively raising the hypothetical possibility that the agency may nevertheless "initiate an enforcement action" against Plaintiffs that would force them to relitigate whether the Proscribed Combination is IIHI in "a lengthy administrative process followed by judicial review." *See* Defts. Br. 44-45. *Third*, and relatedly, if Plaintiffs need to come back to this Court for injunctive relief in the event that HHS did initiate an enforcement action based on the Proscribed Combination despite a declaratory judgment, the Government will inevitably try to argue (erroneously) that the special judicial-review scheme for civil-penalty proceedings precluded this Court from exercising jurisdiction to enforce its declaratory judgment. *See supra* at 21 n.6. Issuing an injunction now will foreclose all of these issues. Indeed, if this Court were to choose between issuing an injunction and a declaratory judgment, Fifth Circuit precedent favors the former. *See EEOC*, 933 F.3d at 451-52 ("Because we affirm the injunction, we decline to consider Texas's DJA claim.").

Finally, recognizing that "the Fifth Circuit has held that vacatur is generally an appropriate remedy in an APA action," the Government simply "preserve[s] all arguments that the APA does not permit vacatur" of the Revised Bulletin. *See* Defts. Br. 45 n.8. As the Government makes no arguments against vacatur of the Revised Bulletin's rule on the Proscribed Combination other than one it admits is foreclosed by binding precedent, this Court can and should grant vacatur on that basis alone. And vacatur would be especially warranted if this Court were to decline to issue an injunction as a matter of equitable discretion. *Cf. Nuziard*, 2024 WL 965299, at *44 (exercising remedial discretion not to vacate agency action "[b]ecause a declaratory judgment *and an injunction* … will remedy Plaintiffs' injuries" (emphasis added)).

In sum, this Court should enter the following relief:

(1) a permanent injunction that Defendants may not enforce against Plaintiffs the rule that the Proscribed Combination constitutes IIHI, as formulated in either the Original Bulletin or the Revised Bulletin;

(2) a declaratory judgment that the Original Bulletin and the Revised Bulletin each adopted a rule concerning the Proscribed Combination that exceeds HHS's authority under the IIHI definition in HIPAA and its implementing regulations; and

(3) an order vacating the Revised Bulletin with respect to its rule concerning the Proscribed Combination.

Plaintiffs will submit a revised Proposed Order to this Court along with this brief, as the version submitted with their opening brief is outdated in light of HHS's issuance of the Revised Bulletin.

CONCLUSION

This Court should deny summary judgment to Defendants, grant summary judgment to Plaintiffs, and enter the relief requested above.

April 11, 2024

Respectfully submitted,

/s/ Hashim M. Mooppan
Hashim M. Mooppan* (DC 981758)
Rebekah B. Kcehowski* (PA 90219)
Audrey Beck* (DC 1739917)
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939
(202) 626-1700 (fax)
hmmooppan@jonesday.com
rbkcehowski@jonesday.com
abeck@jonesday.com
* *Pro hac vice*

Jonathan D. Guynn (TX 24120232)
JONES DAY
2727 N. Harwood St., Ste. 500
Dallas, Texas 75201
(214) 220-3939
(214) 969-5100 (fax)
jguynn@jonesday.com

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of April, 2024, a true and correct copy of this document was served electronically by the Court's CM/ECF system on all counsel of record.

/s/ Hashim M. Mooppan
Hashim M. Mooppan
Counsel for Plaintiffs